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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,508	09/08/2003	Eliezer Zomer	089918-020600	9324

67395 7590 07/18/2008

GREENBERG TRAURIG, LLP
200 PARK AVE.
P.O. BOX 677
FLORHAM PARK, NJ 07932

EXAMINER
OLSON, ERIC

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
07/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/657,508	ZOMER ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17,19,20 and 22-36* is/are pending in the application.

4a) Of the above claim(s) *1-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15,17,19,20,22-27,29-32 and 36* is/are rejected.

7)☒ Claim(s) *33-35* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted February 26, 2008 wherein claims 13, 17, 19, 20, 22, 28, and 29 are amended and new claims 31-36 are introduced. This application was filed September 8, 2003, and makes no priority claims.

Claims 1-15, 17, 19, 20, and 22-36 are pending in this application.

Claims 13-15, 17, 19, 20, and 22-36 as amended are examined on the merits herein.

Applicant's amendment, submitted February 26, 2008, with respect to the rejection of instant claims 25-27 under 35 USC 112, second paragraph for lacking antecedent basis for methods involving nonproteinaceous chemotherapeutic agents, has been fully considered and found to be persuasive to remove the rejection as the base claim has been amended to include nonproteinaceous chemotherapeutic agents. Therefore the rejection is withdrawn.

Applicant's amendment, submitted February 26, 2008, with respect to the rejection of instant claims 17 and 28 under 35 USC 112, second paragraph for being indefinite because they claim a method which comprises a chemical compound, has been fully considered and found to be persuasive to remove the rejection as the base claim has been amended to specify that it is the pharmaceutical mixture, and not the method as a whole, which comprises leucovorin. Therefore the rejection is withdrawn.

Applicant's amendment, submitted February 26, 2008, with respect to the rejection of instant claims 28 under 35 USC 112, first paragraph for lacking enablement for a therapeutic method in which leucovorin is administered in combination with a proteinaceous chemotherapeutic agent, has been fully considered and found to be persuasive to remove the rejection as the base claim has been amended to specify that the composition includes a nonproteinaceous chemotherapeutic agent. Therefore the rejection is withdrawn.

Applicant's amendment, submitted February 26, 2008, with respect to the rejection of instant claims 28 under 35 USC 112, first paragraph for lacking written description for a therapeutic method in which leucovorin is administered in combination with a proteinaceous chemotherapeutic agent, has been fully considered and found to be persuasive to remove the rejection as the base claim has been amended to specify that the composition includes a nonproteinaceous chemotherapeutic agent. Therefore the rejection is withdrawn.

Applicant's amendment, submitted February 26, 2003, with respect to the rejection of instant claims 13-15 and 25-27 under 35 USC 102(b) for being anticipated by Lee et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the pharmaceutical

composition be administered other than orally and the dosage form of Lee et al. is specifically intended for oral administration. Therefore the rejection is withdrawn.

Applicant's amendment, submitted February 26, 2003, with respect to the rejection of instant claims 13-15, 22, 25-27, and 29 under 35 USC 102(e) for being anticipated by Simard et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the pharmaceutical composition be administered other than orally and the dosage form of Simard et al. is specifically intended for oral administration. Therefore the rejection is withdrawn.

Applicant's arguments, submitted February 26, 2003, with respect to the rejection of instant claims 13, 22-24, 29, and 30 under 35 USC 102(b) for being anticipated by Boving et al., has been fully considered and found to be persuasive to remove the rejection as the reference is not seen to teach a composition containing galactomannan and a chemotherapeutic agent as separate molecules. Therefore the rejection is withdrawn.

Applicant's amendment, submitted February 26, 2003, with respect to the rejection of instant claims 19 and 20 under 35 USC 103(a) for being obvious over Lee et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the pharmaceutical composition be

administered other than orally and the dosage form of Lee et al. is specifically intended for oral administration. Therefore the rejection is withdrawn.

Applicant's amendment, submitted February 26, 2003, with respect to the rejection of instant claims 19 and 20 under 35 USC 103(a) for being obvious over Simard et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the pharmaceutical composition be administered other than orally and the dosage form of Simard et al. is specifically intended for oral administration. Therefore the rejection is withdrawn.

Applicant's arguments, submitted February 26, 2003, with respect to the rejection of instant claims 19 and 20 under 35 USC 103(a) for being obvious over Boving et al., has been fully considered and found to be persuasive to remove the rejection as the reference is not seen to teach a composition containing galactomannan and a chemotherapeutic agent as separate molecules. Therefore the rejection is withdrawn.

Applicant's amendment, submitted February 26, 2003, with respect to the rejection of instant claim 17 under 35 USC 103(a) for being obvious over Lee et al. in view of Jakobsen et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the pharmaceutical composition be administered other than orally and the dosage form of

Lee et al. is specifically intended for oral administration. Therefore the rejection is withdrawn.

Applicant's amendment, submitted February 26, 2003, with respect to the rejection of instant claim 17 under 35 USC 103(a) for being obvious over Simard et al. in view of Jakobsen et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the pharmaceutical composition be administered other than orally and the dosage form of Simard et al. is specifically intended for oral administration. Therefore the rejection is withdrawn.

Applicant's amendment, submitted February 26, 2003, with respect to the rejection of instant claim 17 under 35 USC 103(a) for being obvious over Lee et al. in view of Van der Bongard et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the pharmaceutical composition be administered other than orally and the dosage form of Lee et al. is specifically intended for oral administration. Therefore the rejection is withdrawn.

The following new grounds of rejection are introduced:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13, 14, 19, 20, 22, 25, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al. (US patent 5733572, cited in PTO-892)

Unger et al. discloses gas-filled microspheres for topical or subcutaneous application to a selected tissue of a patient to deliver pharmaceutical or cosmetic ingredients. (column 5 lines 35-63) Because these microspheres are a drug delivery system they are seen to have the effect of improving the biodistribution of the applied agent compared to the result if it were to be administered alone without a delivery system. The size, solubility, and heat stability of the microspheres can be controlled by adding stabilizing agents including guar gum. (column 18 lines 5-10 and 42-43) The microspheres can be used to deliver nonproteinaceous therapeutic agents such as prednisone, prednisolone, and triamcinolone, (column 21 lines 15-18) and also monoclonal anti-tumor antibodies that are reasonably considered to be proteinaceous chemotherapeutic agents. (column 22 lines 10-21) Furthermore prodrugs of free radicals can be administered in the microspheres as chemotherapy agents. (column 25 lines 46-60) Unger et al. does not specifically disclose a composition containing both a proteinaceous and a non-proteinaceous chemotherapeutic agent, or a composition

having a ratio of between 10:1 and 1:10 or 6:1 and 1:3 of galactomannan to chemotherapeutic agent.

It would have been obvious to one of ordinary skill in the art at the time of the invention to formulate the microspheres of Unger et al. containing both a non-proteinaceous agent and a proteinaceous agent, And additionally to use the specific ratios of galactomannan to therapeutic agent recited in instant claims 19 and 20. One of ordinary skill in the art would have been motivated to combine the two agents because they are each known individually to be useful in this invention, and therefore would be expected to be useful in combination as well. Combining two known therapeutic agents into a single dosage form is well within the ordinary and routine level of skill in the art. Furthermore, as regards the specific ratio of galactomannan to chemotherapeutic agent, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. In the absence of unexpected properties not predicted by the prior art, this is the product not of innovation but of ordinary skill and common sense.

Therefore the invention taken as a whole is *prima facie* obvious. Because Applicant's amendment submitted February 26, 2008 necessitated this new ground of rejection, the rejection is made **FINAL**.

Claims 13-15, 19, 20, 22-27, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoo (US patent 7166299, cited in PTO-892) in view of Merck.

(The Merck Manual of Diagnosis and Therapy, Seventeenth Edition, reference included with PTO-892)

Yoo discloses compositions comprising a solubilized bile acid or bile salt, a pharmaceutical, and a high molecular weight non-starch polysaccharide. (column 8 lines 5-28) Pharmaceuticals that can be used in this invention include fluorouracil (column 13 line 15) and interferon alpha, (column 13 line 16) Non-starch polysaccharides include guar gum, which is a galactomannan. (column 11 lines 60-61) The compositions can be administered in a variety of manners other than orally, fir example injections or topical administration. (column 10 lines 38-41) Yoo does not specifically disclose a composition containing both a proteinaceous and a non-proteinaceous chemotherapeutic agent, or a composition having a ratio of between 10:1 and 1:10 or 6:1 and 1:3 of galactomannan to chemotherapeutic agent.

Merck discloses that interleukin-2 and interferon-alpha can be used as cancer therapeutic agents. (p. 984, right column, paragraphs 3-4, p. 985, right column last paragraph – p. 986 left column first paragraph) Merck also discloses the chemotherapeutic agent fluorouracil as a cancer therapeutic agent. (p. 990, table 144-2)

It would have been obvious to one of ordinary skill in the art at the time of the invention to formulate the microspheres of Unger et al. containing both a non-proteinaceous agent such as fluorouracil and a proteinaceous agent such as alpha-interferon, And additionally to use the specific ratios of galactomannan to therapeutic agent recited in instant claims 19 and 20. One of ordinary skill in the art would have been motivated to combine the two agents because they are each known individually to

be useful in this invention, and therefore would be expected to be useful in combination as well, especially considering that they are both disclosed as cancer chemotherapeutic agents by Merck. Combining two known therapeutic agents into a single dosage form is well within the ordinary and routine level of skill in the art. Furthermore, as regards the specific ratio of galactomannan to chemotherapeutic agent, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. In the absence of unexpected properties not predicted by the prior art, this is the product not of innovation but of ordinary skill and common sense.

Therefore the invention taken as a whole is *prima facie* obvious. Because Applicant's amendment submitted February 26, 2008 necessitated this new ground of rejection, the rejection is made **FINAL**.

Claims 17 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoo in view of Merck as applied to claims 13-15, 19, 20, 22-27, 29, and 30 above, and further in view of Jakobsen et al. (Reference of record in previous action)

The disclosure of Yoo in view of Merck is discussed above. Yoo does not disclose a method comprising further administering leucovorin.

Jakobsen et al. discloses a study of different does intensities of 5-fluorouracil. (p. 526, left column, second paragraph) The patients treated had recurrent colorectal cancer. (p. 526, left column, third paragraph) All treatment groups received fluorouracil in combination with leucovorin. (p. 526, left column fourth paragraph, right column first paragraph)

It would have been obvious to one of ordinary skill in the art at the time of the invention to coadminister the fluorouracil-containing compositions of Yoo with leucovorin, to a patient having colon cancer. One of ordinary skill in the art would have been motivated to combine these two elements because Jakobsen et al. specifically discloses that 5-fluorouracil can be productively co-administered with leucovorin for treating cancer. One of ordinary skill in the art would reasonably have expected success because combining two elements known in the prior art to be useful for treating the same condition is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious. Because Applicant's amendment submitted February 26, 2008 necessitated this new ground of rejection, the rejection is made **FINAL**.

Claims 13-15, 19, 20, 22-27, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oda (Reference included with PTO-892) in view of Merck. (The Merck Manual of Diagnosis and Therapy, Seventeenth Edition, reference included with PTO-892)

Oda discloses the antitumor effect of intraperitoneally administered xanthan gum, or galactomannan. (abstract, p. 5744, table 1, p. 5745, table 2) Oda also discloses a synergistic effect of combinations of galactomannan with chemotherapeutic agents including 5-fluorouracil and bleomycin in a ratio of 50 mg galactomannan to 50 mg fluorouracil for a 1:1 ratio or 12.5mg bleomycin for a 4:1 ratio. (p. 5747, table 4) Oda does not specifically exemplify a method of administering a composition containing both

galactomannan and a chemotherapeutic agent together in a single composition in a pharmaceutically acceptable carrier, or a method utilizing a proteinaceous chemotherapeutic agent.

Merck discloses that interleukin-2 and interferon-alpha can be used as cancer therapeutic agents. (p. 984, right column, paragraphs 3-4, p. 985, right column last paragraph – p. 986 left column first paragraph) Merck also discloses the chemotherapeutic agent fluorouracil as a cancer therapeutic agent. (p. 990, table 144-2)

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer a composition combining xanthan gum with fluorouracil in a 1:1 ratio or bleomycin in a 4:1 ratio and/or a cytokine such as interleukin-2 or interferon alpha. One of ordinary skill in the art would have been motivated to combine galactomannan with fluorouracil or bleomycin because of the synergistic effect observed by Oda. One of ordinary skill in the art would have been motivated to combine galactomannan with IL-2 or interferon alpha because Merck discloses that these cytokines are also useful for treating cancer. One of ordinary skill in the art would reasonably have expected success because combining known therapeutic agents to produce either an additive or a synergistic effect is well within the ordinary and routine level of skill in the art, particularly for cancer chemotherapy.

Therefore the invention taken as a whole is *prima facie* obvious. Because Applicant's amendment submitted February 26, 2008 necessitated this new ground of rejection, the rejection is made **FINAL**.

Claims 17 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oda in view of Merck as applied to claims 13-15, 19, 20, 22-27, 29, and 30 above, and further in view of Jakobsen et al. (Reference of record in previous action)

The disclosure of Oda in view of Merck is discussed above. Oda in view of Merck does not disclose a method further comprising administering leucovorin.

Jakobsen et al. discloses a study of different does intensities of 5-fluorouracil. (p. 526, left column, second paragraph) The patients treated had recurrent colorectal cancer. (p. 526, left column, third paragraph) All treatment groups received fluorouracil in combination with leucovorin. (p. 526, left column fourth paragraph, right column first paragraph)

It would have been obvious to one of ordinary skill in the art at the time of the invention to coadminister the fluorouracil-containing compositions of Oda in view of Merck with leucovorin, to a patient having cancer. One of ordinary skill in the art would have been motivated to combine these two elements because Jakobsen et al. specifically discloses that 5-fluorouracil can be productively co-administered with leucovorin for treating cancer. One of ordinary skill in the art would reasonably have expected success because combining two elements known in the prior art to be useful for treating the same condition is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious. Because Applicant's amendment submitted February 26, 2008 necessitated this new ground of rejection, the rejection is made **FINAL**.

The following rejections of record in the previous office action are maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13, 15, 19, 20, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Klyosov et al. (US patent 6645946, reference of record in previous action)

Klyosov et al. discloses a method for treating cancer comprising administering a chemotherapeutic agent and a galactomannan. (column 2, lines 25-28) The galactomannan used can have a ratio of 2.0-3.0 mannose to 0.5-1.5 galactose or particularly 2.6 galactose to 1.5 mannose, which is the same as the ratio of 1.7:1.0 of the galactomannan used in the claimed invention, as disclosed on p. 24 of the instant specification. (column 2, lines 40-48) In one embodiment the chemotherapeutic agent us 5-fluorouracil. (column 2, lines 56-58) In one embodiment the cancer is colon cancer. (column 2, lines 59-65) The preferred galactomannan has a structure that is the same as that of the claimed invention disclosed on p. 24 of the instant specification. (column 6, lines 1-5) In certain embodiments, a galactomannan having an average molecular

weight of 40-200kD, or alternately 83 kD, is used. (column 5 lines 19-30) The galactomannan and the therapeutic agent can be administered in a ratio of 1:1.9 of galactomannan to fluorouracil. (column 5, lines 31-39) Therefore the invention disclosed by Klysov et al. is the same as that of the claimed invention, and anticipates the claimed invention.

The applied reference has a common assignee and one common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Response to Argument: Applicant's arguments, submitted February 26, 2008, with respect to the above ground of rejection, has been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the addition of Anatole Klyosov as an inventor of the current application and the deletion of Eli Zomer as an inventor serves to render the inventive entity of the current application the same as that of Klysov et al. Although Anatole Klyosov has been added as an inventor to this application, Eli Zomer has not yet been removed as an inventor. Therefore the rejection is maintained and made **FINAL**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17, 32, and 36 are rejected under 35 U.S.C. 103(a) as being obvious over Klyosov et al. (US patent 6645946, reference of record in previous action) in view of Jakobsen et al. (Reference of record in previous action)

The disclosure of Klysov et al. is discussed above. Klysov et al. does not disclose a method further comprising administering leucovorin or a method in which the galactomannan has a molecular weight of about 40-60 kD.

Jakobsen et al. discloses a study of different does intensities of 5-fluorouracil. (p. 526, left column, second paragraph) The patients treated had recurrent colorectal cancer. (p. 526, left column, third paragraph) All treatment groups received fluorouracil in combination with leucovorin. (p. 526, left column fourth paragraph, right column first paragraph)

It would have been obvious to one of ordinary skill in the art at the time of the invention to coadminister the fluorouracil-containing compositions of Klysov et al. with leucovorin, to a patient having cancer, for example colon cancer. One of ordinary skill in the art would have been motivated to combine these two elements because Jakobsen et al. specifically discloses that 5-fluorouracil can be productively co-administered with leucovorin for treating colon cancer. One of ordinary skill in the art

would reasonably have expected success because combining two elements known in the prior art to be useful for treating the same condition is well within the ordinary and routine level of skill in the art.

As regards the limitation of instant claims 32 and 36, wherein the molecular weight of the galactomannan is 40-60 kD, when the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05 [R-1]. In the instant case, the prior art discloses a range of 40-200 kD which encompasses the claimed range of 40-60 kD. Selecting the appropriate embodiment of galactomannans from the broader prior art disclosure of molecular weights is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

The applied reference has a common assignee and one common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application

and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Response to Argument: Applicant's arguments, submitted February 26, 2008, with respect to the above ground of rejection, has been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the addition of Anatole Klyosov as an inventor of the current application and the deletion of Eli Zomer as an inventor serves to render the inventive entity of the current application the same as that of Klysov et al. Although Anatole Klyosov has been added as an inventor to this application, Eli Zomer has not yet been removed as an inventor. Therefore the rejection is maintained and made **FINAL**.

Conclusion

Claims 13-15, 17, 19, 20, 22-27, 29-32, and 36 are rejected. Claims 33-35 are objected to for depending from a rejected base claim but would be allowable if rewritten in independent form incorporating all the limitations of the rejected base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
7/7/2008

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623